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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,646	12/12/2003	Reinhard Ebner	PF403D2	9581

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,646	EBNER ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 20, 22 drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence at least 95% identical to a sequence selected from the group consisting of a nucleotide sequence encoding the ependymin polypeptide of SEQ ID NO: 2 and fragments and epitopes thereof; wherein the polynucleotide has the nucleic acid sequence of SEQ ID NOs: 1, 15, 16, 17, 18, 19, 20 and fragments thereof.; vectors; recombinant host cells, method of making said polypeptide; classified in class 435, subclass 69.1, 320.1, 252.3, 325; class 536, subclass 23.1, 23.5.

Should Group I be elected, applicants are required to select one polynucleotide sequence from claims 2 and 22; and identify the value n and m and select one amino acid sequence from claim 5. Each of the polunucleotides and encoded polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **It is emphasized that this is a restriction of distinct invention, not election of species.**

II. Claims 17, 18, 21 drawn to an isolated ependymin polypeptide comprising an amino acid sequence at least 95% identical to a sequence selected from the group consisting of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2; a polypeptide fragments or epitopes thereof; classified in class 530, subclass 350, 300.

Should group II be elected, applicants are required to select one amino acid sequence from claim 18. Each of the polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **It is emphasized that this is a restriction of distinct invention, not election of**

species.

III. Claim 19, drawn to an antibody that selectively binds to the ependymin polypeptide of claim 17; classified in class 530, subclass 387.1+.

IV. Claim 23, drawn to a method of treating a patient by administering the polypeptide of claim 1; classified in class 530, subclass 350, 300; class 514, subclass 2.

V. Claim 24, drawn to a method of identifying compounds which bind to and inhibit activation of polypeptide of claim 1 by contacting cells which express a receptor for the polypeptide of claim 1 with a candidate compound and assaying said cellular response; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.1

VI. Claim 25, drawn to a method of diagnosing a disease related to an under expression of polypeptide of claim 1 by determining presence or absence of a mutation in the polynucleotides of claim 1; classified in class 536, subclass 23.1, 24.3, 24.31; class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product of Invention II can be made by another materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group I is a separate and distinct chemical entity from the antibody of group III. The nucleic acid of Group I does not encode the antibody of Group III and is not used for the practice of Group III. Therefore the inventions are distinct.

Invention I is unrelated to inventions IV, V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group I is not used for the practice of the methods of groups IV and V. In the instant case the different inventions are directed to processes whose end results are materially distinct from the recombinant process of invention I. The results of the processes are directed to different ends. The DNA of group I and the binding partner of group V are related by virtue of the protein that is encoded by the DNA and necessary for the production of the binding partner. However, the DNA itself is not necessary for binding partner production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

Inventions I and invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used on other, materially distinct process, such as in methods for the recombinant production of a protein or in nucleic acid hybridization assays. Therefore, these inventions are distinct.

The polypeptide of group II is related to the antibody of group III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complimentarity of the two, they are distinct inventions. The protein can be used in other materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a natural ligand of the protein if it is a receptor. Further, the polypeptide of Group II and the antibody of

group III are structurally and functionally distinct molecules with different amino acids compositions. Therefore the inventions are distinct.

Invention II is related to inventions IV and V as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used in other materially distinct processes from those set forth in the claims of Groups IV and V such as the immunization of a mammal for production of antibody. The protein of group II and the binding partner of group V are related by virtue of the protein that is necessary for the production of the binding partner. However, both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not necessary for the practice of invention of VI. Therefore the inventions are distinct.

Inventions III and inventions IV, V, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of III is not necessary for the practice of inventions of IV, V and VI. The antibody of group III and the binding partner of group V are related by virtue of the protein of group II, which is necessary for the production of the binding partner. However, both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The inventions IV and V are related by virtue of the polypeptide, which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions IV, V and invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of inventions IV and V is not necessary for the practice of invention VI, and nucleic acid of invention VI is not necessary for the practice of inventions IV and V. Therefore the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Mark Hyman on August 24, 2005 and March 16, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions

on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.
April 4, 2006

Jon Weber
Supervisory Patent Examiner